

Ser. No. 10/048,205
Amdt. dated October 23, 2003
Reply to Office action of April 23, 2003

Amendments to the Specification:

Please replace the paragraph beginning at page 4, line 3 with the following amended paragraph:

Barbs formed on the proximally facing edge of the finished implant may be formed on the ribbon prior to winding into its coiled shape. Preferably, the ribbon is formed having barbed shapes along at least one edge of the ribbon by an etching process. A number of ribbons may be etched on a sheet of suitable material, such as stainless steel, at once. After the ribbons are formed on the sheet of material, they may be individually detached from the sheet and wound on a spring winding machine to form a coil by conventional spring winding techniques.

Please replace the paragraph beginning at page 5, line 6, with the following amended paragraph:

FIG. 2 is a partial sectional view of the tissue implant device shown in FIG. 43 1:

Please replace the paragraph beginning at page 5, line 24, with the following amended paragraph:

The implant devices of the present invention are particularly useful in treating ischemic tissue such as that which often occurs in a myocardium of the heart. The implant device may be inserted into the myocardium through the epicardial surface at an entry site such that the device extends the majority of the thickness of the myocardium towards endocardial surface.

Please replace the paragraph beginning at page 5, line 29, with the following amended paragraph:

FIG. 1 shows an embodiment of a tubular implant device. The canted coil device 40 is formed from a filament 42 of rectangular cross-section such as a strand of flat wire. The implant device has a proximal portion 52 and a distal portion 53. As shown in FIG. 2, the coil is formed so that the major cross-sectional axis 47 of the rectangular wire is oriented at an acute angle to the longitudinal axis 50 of the coil 40. The

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orientation gives each turn 46 of the coil a projecting edge 44, which tends to claw into tissue to serve as an anchoring mechanism for the device.

Please replace the paragraph beginning at page 6, line 16, with the following amended paragraph:

FIG. 4 shows a preferred embodiment of the wrapped ribbon device 62 having a plurality of barbs 64 formed on the proximally facing edge ~~66~~ 63 of the ribbon. The device may only have one barb, but a plurality of barbs is preferred. Each barb has a tapering penetrating shape configured to claw into tissue to resist migration of the device. The barbs may be a variety of shapes such as the curved shape shown in the figures or a sharp pointed shape (not shown). Barbs 64 formed on the spring embodiment shown in Figure 1 tend to project radially outward from the longitudinal axis of the device at an acute angle, as shown in Figure 4. The radial projection of the barbs may help to anchor the implant within tissue.

Please replace the paragraph beginning at page 6, line 25, with the following amended paragraph:

Alternatively, as shown in Figure 5, the spring device 68 may have coil 70 oriented such that the major ~~their~~ axis is parallel to the longitudinal axis of the device and barbs 64 are curved radially outward from the proximally facing edge 72 of each coil 70. The barbs may be curved by bending prior to wrapping of the ribbon into a coil form.

Please replace the paragraph beginning at page 6, line 30, with the following amended paragraph:

Ribbon material having integrally formed barbs may be formed by variety of methods; however, chemically etching of the ribbon having barbed shapes is preferred. FIG. 6 shows a top view of a sheet 76 of material having a plurality of ribbon forms 78 that have been etched through its surface. FIG. 7 shows a magnified view of a single ribbon form 78 comprising a linear ribbon form 79 of a plurality of barb 64, which will

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ultimately be wrapped into the spring device. Each form 78 remains joined to the sheet 76 after etching by links 77. Ribbon forms are preferably created by a photo etching process. In this process, a photo resistant coating is first applied over the entire sheet of material. Preferably a sheet of stainless steel material is used to having a thickness equivalent to the desired thickness of the final ribbon product as has been defined above. After application of the coating a template having the desired pattern of shapes (a plurality of ribbons having barbs with spare material between each ribbon form) is placed over the sheet. Next ~~the sheet~~ light is applied to the sheet to remove the protective coating from areas of the sheet where material is to be removed. The resultant sheet etchant protective coating remains only over areas where material is to remain. The sheet is then exposed to a chemical etchant which removes material from the sheet in the unprotected areas. The resultant 76 sheet shown FIG. 6 has numerous perforations where material has been removed the chemical etchant process provides a quick and economical way to form numerous pieces of ribbon stock having accurately formed barbs. The ribbon forms an easily finished sheet by breaking or cutting links 77. The ribbon may be wrapped in to the helical spring implant device as is described above.

Please replace the paragraph beginning at page 7, line 21, with the following amended paragraph:

The implant devices of the present invention may be delivered to their intended tissue location surgically. FIGS. 8A - 8C show an example of a surgical delivery device that may be used to deliver the implants into tissue such as that of the myocardium of the heart. The delivery device, shown in FIG. 8A, comprises an obturator 80 that includes a main shaft 82, by which it can be gripped and manipulated. The distal end 81 of the shaft 82 is shown in detail in FIG 8B and includes a reduced diameter device support section 84 having a sharp distal tip 86 adapted to pierce tissue. The diameter of the shaft segment 84 is such as to fit closely within the interior of the devices. The proximal end of the segment 84 terminates in a shoulder 88 formed at the junction of a proximally adjacent, slightly enlarged diameter portion 90 of the shaft. The distal end of

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the device support segment 84 may include a radially projecting pin 92 dimensioned to project and fit between adjacent turns of the coils of a device. The pin 92 engages the coils in a thread-like fashion so that after the assembly has been inserted into the tissue, the obturator 80 can be removed simply by unscrewing the obturator to free it from the implanted coil. Alternatively, the obturator may be configured without the projecting pin 92 so that the device can be slipped on and off the obturator, without screwing. When an implant device 2 40 is mounted on the obturator 80, as is shown in FIG. 8C the proximal end of the device may bear against the shoulder 88, and ~~the tail~~ 28 a tail, if so equipped may extend along the segment 90 of the obturator.